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System and Method for Recruitment of Candidates for Clinical Trials While Maintaining Security

BACKGROUND OF THE INVENTION

Field of the Invention

The present invention relates generally to a system for recruitment of candidates for clinical trials, and in particular to the recruitment of candidates, such as individuals who are afflicted with AIDS/ HIV positive, who require a certain level of privacy concerning access to their personal and medical information. The invention is also directed to a method of using the same.

Description of Related Art

Before a drug or medical technique is approved for use on the public at large, it is administered to a limited number of patients who participate in clinical trials. It is necessary when selecting individuals to participate in the clinical trials to choose only those individuals who meet particular exclusion and inclusion criteria for a specific trial. Selection of candidates to participate in such clinical trials may depend on factors, such as the gender, age, symptoms, prognosis, and previous medical treatments.

Conventional methods of solicitation, such as newspaper and magazine advertisements have heretofore been widely used to solicit individuals to participate in clinical trials. By way of example, an advertisement may be directed to individuals who suffer from

asthma and are currently on steroids. Individuals who meet the requirements specified in the advertisement are invited to call a particular number or inquire to be considered as a candidate to participate in the clinical trial.

With the advent of the Internet, web sites, such as Koop.com, Americasdoctor.com and Intertrials.com, have electronically implemented the conventional solicitation process for on-line recruitment of candidates for clinical trials. The procedures used by these conventional web sites, however, are not suitable for receiving personally identifiable medical data concerning patients who suffer from diseases, ailments, disorders, and medical conditions, such as HIV/AIDS, that require a certain level of security against potential unwanted dissemination of personal and/or medical information, and the right to remove one's name from a list of volunteers. Not only is the privacy of such data desirable from the point of view of the individual and their family, but legislation and regulations mandate the level of security to be accorded personal and medical information. For example, the federal department of Health and Human Services has recently promulgated regulations concerning the level of security to be accorded transmission of medical records and personal data, and in particular New York legislation requires that prior to dissemination of medical information the individual sign a release form and that an opt out method be available when recruiting candidates for clinical trials. Other countries have recently adopted guidelines, such as the European Union data directive concerning procedural aspects of the dissemination of personal and medical information.

It is therefore desirable to develop a system and method for online recruitment of candidates for clinical trials and research studies that overcomes the aforementioned problems.

Summary of the Invention

The following terms used to describe the invention are defined as follows:

"End user" is an individual that accesses the web site for on-line recruitment of candidates for clinical trials.

"Volunteer" is an end user that visits and registers with the web site to be considered as a potential candidate for a clinical trial.

"Candidate" is a volunteer selected to take part in a clinical trial.

"Web site" is a server application which accepts connections from client programs, such as browsers, that allow a remote end user to access and register as a volunteer for on-line recruitment of candidates for clinical trials.

The terms "clinical trials" and "research studies" are used interchangeably throughout the description and the claims.

It is an object of the present invention to develop an on-line click wrap agreement for the release of medical and personal information by end users prior to volunteering to be considered as a potential candidate for clinical trials. The agreement authorizes the release of the end user's medical and/or personal information to representatives of the clinical trials and research studies for which the volunteer may be considered as a potential candidate. After receiving the end user's consent to the click wrap agreement an electronic survey form is generated by a secure server and displayed at the end user's computer terminal. Responses by the end user to the survey form are kept secure as much as possible while being transmitted from the computer terminal across the network to the server and while stored and accessed only by authorized personnel at the central office.

The invention is directed to a method for using a system for on-line recruitment of candidates for clinical trials in which an end user's consent to an electronic agreement relating to volunteering as a potential candidate for a clinical trial and the release of at least one of medical and personal information is received by a central office.

In addition, the invention relates to a system for on-line recruitment of candidates for clinical trials over a network including a secure server for generating an electronic agreement, and one or more computer terminals on which is displayed the electronic agreement. The computer terminal is used by an end user to provide their consent to the electronic agreement to volunteer as a potential candidate for a clinical trial and release medical and/or personal data. In this configuration the server and computer terminals are connected via a network.

Brief Description of the Drawing

The foregoing and other features of the present invention will be more readily apparent from the following detailed description and drawings of illustrative embodiments of the invention wherein like reference numbers refer to similar elements throughout the several views and in which:

Figure 1 is an exemplary high-level diagram of a secure system for on-line recruitment of candidates for clinical trials in accordance with the present invention;

Figure 2 is an exemplary flow chart of the operating steps of the secure system for on-line recruitment of candidates for clinical trials in accordance with the present invention;

Figures 3a-3f is an exemplary Health Survey form display screen in accordance with the present invention; and

Figure 4 is an exemplary Opt-out display screen in accordance with the present invention.

Detailed Description of the Invention

By way of example, the discussion of the system and method in accordance with the present invention is directed to on-line recruitment of volunteers as potential candidates for clinical trials relating to drugs and/or medical treatment of individuals suffering from AIDS/HIV. It should be noted, however, that the recruitment is also applicable to other diseases, ailments, disorders, and medical conditions, such as infectious diseases, or infertility, in which individuals suffering therefrom are stigmatized and thus, would benefit from the implementation of optimum security measures. In addition, the system is also advantageous in view of recent federal and state laws and regulations that mandate the level of security to be accorded the transmission and dissemination of personal and medical data.

Figure 1 is a high-level diagram of a system or server 100 having a memory device 105. System 100 is connected to a central or main office 110 having a memory device 115. Although the main office 110 is shown in Figure 1 as separate and remote from the system 100, the two devices may be in a single location or unit. System 100 is accessed by multiple computer

terminals 125, 130, 135 connected via a network 120, such as the Internet. While the system and method in accordance with the present invention is described in the context of the Internet or world wide web, it can also be used in other network environments, such as a local area network (LAN), Intranet, wide area network (WAN), or various wireless technology platforms, where the system and software are accessible by both subscribers and end users alike from remote locations. Only three computer terminals are shown, however, any number of computers may be connected to network 120 through known communication interfaces, such as an external or built-in modem (not shown). End users may access the system from any computer terminal throughout the world having appropriate network Internet access and software, such as a web browser. The system 100 uses a secure server, such as Netscape™, using secure socket layer (SSL) protocols or alternative security means. System 100 may be designed so that an end user must employ a web browser that supports SSL. In a preferred embodiment, system 100 notifies the end user if their web browser does not support SSL or if the particular version of the Internet access software installed by the end user falls below a minimum acceptable level of security functionality.

Figure 2 is an exemplary flow chart of the operation of the secure system for on line recruitment of candidates for clinical trials and research studies. The end user visits the web site and sever 100 automatically generates an introductory home page displayed at the user's computer terminal briefly describing the nature of the services being provided at the web site. In a preferred embodiment, the end user is able to access additional information, e.g., publications, concerning some of the pros and cons associated with participating in a clinical trial, to assist the end user in their decision whether or not to register as a volunteer.

In step 210, server 100, in response to the end user selecting or clicking on a button or icon to proceed or continue, generates a Participation Agreement that is displayed at the end user's computer terminal. The agreement may be drafted, as desired, to cover all legal issues, such as the liabilities and duties of each party. By way of example, the Participation Agreement may include one or more provisions directed to (1) the voluntary nature of the information being provided by the volunteer; (2) the disclaimer of any guarantee of information being provided to clinical researchers or labs; (3) duties on the part of the service to take all reasonable measures

to maintain the confidentiality of the data entered by the volunteer; (4) limitations of liability on the part of the service; (5) compensation and ownership rights; (6) independence of the service with respect to the clinical researchers and labs; (7) the volunteer's informed consent upon completing the Health Survey form; (8) authorization by the volunteer to release all data provided in response to the Health Survey form; (9) applicable governing law for disputes which may arise under the contract; and (10) additional provisions directed to laws and regulations in specific states. The end user agrees or consents to be bound by the terms and conditions presented in the Participation Agreement by clicking on an acceptance button or icon before being considered as a possible candidate for a clinical trial or research study.

Upon agreeing or consenting to the terms of the Participation Agreement, for example, by clicking on the acceptance button or icon, in step 220, server 100 produces a Health Survey form display screen at the computer terminal of the end user. Figures 3a-3f is an exemplary Health Survey form display screen requesting that the end user enter personal and/or medical information about themselves. By way of example in Figures 3a-3f, the end user may be asked personal questions such as their age, sex, name, address, telephone number, and medical questions, such as, their health condition status, how long they have been HIV positive, specific test results, medications the end user is currently taking or has taken in the past, infections or complications the end user may have had or currently has. Figure 3 also shows some illustrative examples of the type of responses that may be entered by the end user. For example, the end user may be requested to enter text and/or numerical information in a data entry field, select one or more entries from a list of available options, select one or more entries from a pull down menu, or any combination thereof. The Health Survey form may therefore be designed, as desired, depending on such factors as the nature of the particular disease, ailment, disorder or medical condition to which the research studies and clinical trials are directed. Representatives of a registered clinical trial or research study may adapt the questions presented in the Health survey form in accordance with inclusion or exclusion criteria for their particular study.

In Figure 2, after the end user has responded to all of the questions in the Health Survey form and clicked on a "Submit" button or icon, in step 230, the data entered is

automatically encrypted by the volunteer's web browser software before being transmitted to the server 100. Thus, any potential hackers attempting to intercept the confidential information during transmission between the volunteer's computer terminal and the server 100 will be unable to decipher the data.

Thereafter, in step 240 the encrypted data is transmitted from the end user's computer terminal to the server 100 via network 120. In a preferred embodiment, if the end user has not entered a response to one or more questions, then an error message is displayed with the subject matter of the unanswered questions and prompts the end user to go back to the previous screen to correct these responses.

After agreeing to the Consent Agreement and completing the Health Survey form, to confirm that the information provided in response to the Health Survey will be sent directly to the system or server 100, the volunteer may access a digital certificate procured, for example, by Verisign™, to verify communication between the end user's browser and server 100. Alternatively, a digital certificate may be automatically generated in response to the user completing the Health Survey form.

In steps 250-260 of Figure 2, the encrypted responses to the Health Survey form received at the server 100 are decrypted and stored in memory device 105. The decrypted data stored in memory device 105 is subject to access by potential hackers who gain access to that server to observe the data while in its decipherable state. Server 100 circumvents this potential problem by implementing one or more precautionary measures. In particular, server 100 may be programmed to restrict access to the server to only a minimum number of trusted and screened employees. Security policies and procedures may be implemented to ensure that unauthorized personnel never access the decrypted information received by the server.

In steps 270-280, server 100 processes the volunteer's data responses to the Health Survey, preferably using a specification, such as Common Gateway Interface (CGI) "scripts", to extend the service and capabilities of the web server, and automatically encrypts the processed data using Pretty Good Privacy (PGP) or some other known shareware encryption protocol. Thereafter, in step 290, immediately after encryption, server 100 destroys or purges the

unencrypted volunteer's data stored in memory device 105, which, in turn, is replaced with the encrypted processed data. Encrypted processed data stored in memory device 105 is then transmitted from server 100 to the main or central office 110, in step 300.

At the main or central office 110, access to the volunteer's data is restricted to limited personnel. In step 310, the volunteer's data is stored in encrypted form in memory 115. Thereafter, in step 320, the data stored in memory 115 is retrieved and decrypted only when requested by authorized personnel. Encryption keys are preferably stored on an external memory device, such as a floppy disk, a compact disk, or some other storage device, and kept under surveillance, e.g., under lock and key, to which only authorized employees have access.

At any point in time a volunteer may opt-out by removing their name from the database of volunteers. Figure 4 is an exemplary Opt-Out form display screen. The volunteer is preferably asked to enter their first name, last name, and date of birth. Any information may be requested so long as the particular volunteer to be removed can be properly identified. Additional information may be used to properly identify the volunteer, such as the maiden name of the volunteer's mother. It is contemplated that the most basic information, e.g., the full name and date of birth of the volunteer, may be initially requested and that additional information will be solicited only if the database identifies multiple matches from the database of volunteers. In an alternative embodiment, the volunteer when registering with the service is assigned a unique identification number that may be subsequently entered by the volunteer when requesting to be removed from the list of potential candidates. In this alternative embodiment, if the volunteer could not recall their identification number, other means for identifying the volunteer as discussed above may be employed.

Researchers and lab technicians interested in accessing the database of volunteers to obtain candidates for its clinical trials and/or research studies register with the central office 110. The registration process may be performed on-line by accessing the web site or via some other communication medium, such as by filling out a printed registration form. By way of example, the registration form may request the name of an authorized officer conducting the research, the subject matter being researched, the medical professionals associated with the

research, and the criteria used in the selection of candidates as well as the number of candidates being sought. The completed registration form is forwarded to the central office. In a preferred embodiment of the invention, the central office verifies the credentials and legitimacy of the clinical trial and research study being conducted before establishing an affiliation. Once initial approval is provided, a representative on behalf of the clinical trial or research study must enter into an agreement to be bound by the rules set forth by the central office concerning the prevention against unwanted dissemination of the personal and medical records of its volunteers. A registered clinical researcher or lab may modify the information requested in the Health Survey form based on their own particular needs.

After a volunteer has been selected as a potential candidate for a clinical trial or research study, they are contacted directly by a representative of the clinical trial or research study. All communication is conducted directly between the two parties, without intervention by the central office. In an alternative embodiment, direct contact between a representative on behalf of the clinical trial or research lab and the volunteer is not initiated until the central office first contacts the volunteer and confirms that they still want to be considered as a potential candidate for the particular clinical trial or research study. After confirming that the volunteer stills wishes to be considered as a potential candidate for the particular clinical trial or research study, all communication thereafter would be directly between a representative of the particular clinical trial or research study and the volunteer.

It is desirable to develop a comprehensive security system. Accordingly, additional safeguards are contemplated and within the intended scope of the invention including the use of firewalls or other known security measures. The present invention has been described for recruitment of volunteers as potential candidates for clinical trials or research studies concerning a single disease, e.g., HIV/AIDS. It is, however, contemplated that the server may initially generate a display screen requesting the user to select from a number of diseases, ailments, disorders or medical conditions in which to participate as a volunteer. In this situation the Health Survey form may be modified depending on the particular disease, ailment, disorder or medical condition for which the individual is volunteering.

In the operation of the on-line recruitment system as described above, the volunteer must agree to opt in or opt out of all registered clinical trials or research studies. Alternatively, the system may be adapted so that the server 100 displays a list of all registered clinical trials and research studies that are currently recruiting candidates from which the volunteer may select or target one or more registered clinical researchers/labs that they wish to be listed as a volunteer and be considered as a potential candidate. The volunteer's personal and medical information will only be accessible by those clinical trials and research studies that have been selected by the volunteer.

Thus, while there have been shown, described, and pointed out fundamental novel features of the invention as applied to a preferred embodiment thereof, it will be understood that various omissions, substitutions, and changes in the form and details of the devices illustrated, and in their operation, may be made by those skilled in the art without departing from the spirit and scope of the invention. For example, it is expressly intended that all combinations of those elements and/or steps which perform substantially the same function, in substantially the same way, to achieve the same results are within the scope of the invention. Substitutions of elements from one described embodiment to another are also fully intended and contemplated. It is also to be understood that the drawings are not necessarily drawn to scale, but that they are merely conceptual in nature. It is the intention, therefore, to be limited only as indicated by the scope of the claims appended hereto.